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Is there a future in robot-assisted minimally invasive surgery?

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Outline

- Introduction to Robotic Surgery
  - Reasons for examining the current products
  - State of the practice
  - Competitors
  - Advantages and limitations
- Future alternatives:
  - Technical challenges
  - Economical challenges
- Conclusions

Robotic Surgery

- There are several types of robot-assisted surgical procedures:
  - Orthopedic surgery
  - Neurosurgery
  - Abdominal surgery
  - Ear, Nose, Throat (ENT)
  - Thyroid
  - ....

MAKO

Medtech ROSA

The da Vinci Robot

Here I will focus on minimally invasive interventions, such as those performed with the “da Vinci” surgical robot.

Top of the line da Vinci configuration

Minimally Invasive Procedures

The advantages of Robotic Surgery

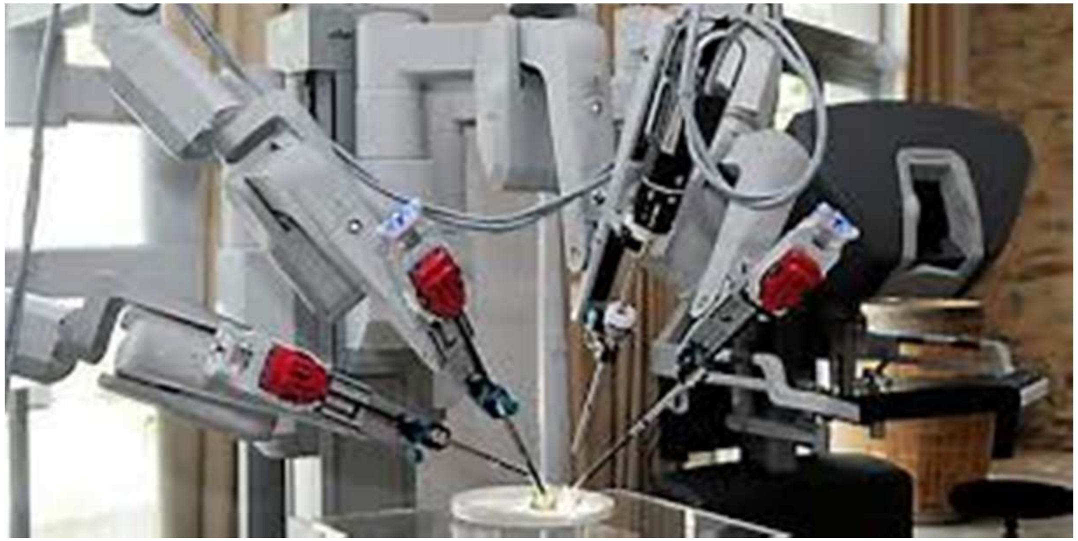
There are basically two main advantages:

perception and dexterity

A surgical robot combines the small instrument size of laparoscopic surgery, with the hand dexterity and visual perception of open surgery. These features allowed a significant improvement in surgical performance even where laparoscopic technique was not too high.

The Key Elements

The surgical robot is the carrier of the instruments and all the “value” of the system lies in the instruments and in the stereo camera



All the rest is “useless” (and cheap) hardware.

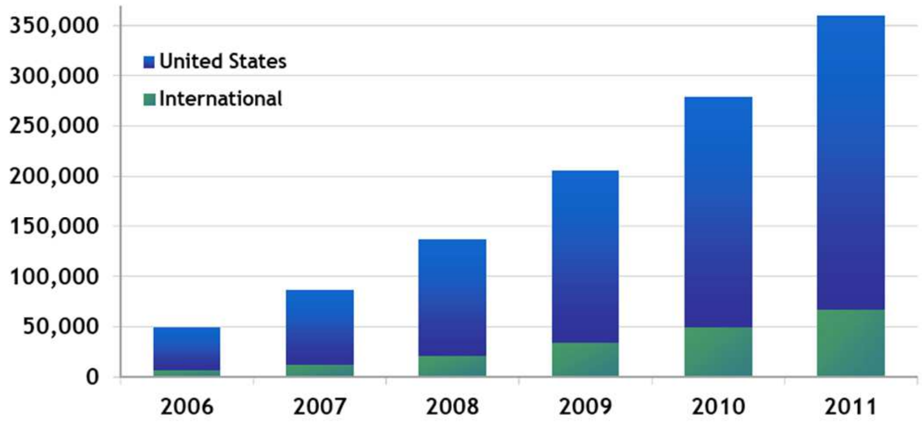
Reasons of da Vinci Success

- Intuitive and apparently easy operation
- Simple training
- Marketing to patients
- Creation of high-tech image
- Selective use of intervention data
- Very accurate control on data dissemination
- Strict protection of hardware and software interfaces

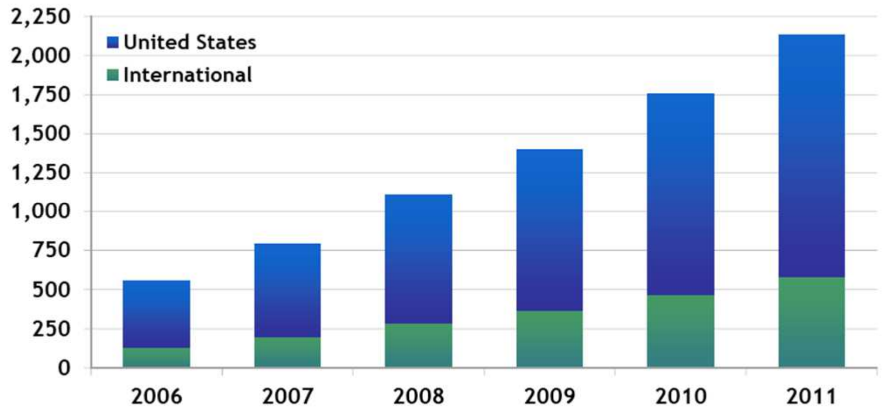
Intuitive Surgical performance

- Intuitive Surgical, manufacturer of the daVinci robot was founded in 1995, IPO 2000
- 2011 Financial Results
  - Revenue – US $1.76B, up 24% from 2010
  - Operating Profit – US $695M, up 25% from 2010, 39.5% of sales
- 2012 Financial Results
  - Revenues - US $ 2.1B, up 24% from 2011
  - Operating Profit US $ 878M, up 26% from 2011, 40.3% of sales.
- 2013 Financial Results
  - First Half Revenues US $ 1.9B, up 15% from the first half of 2012.
- Approximately 360,000 *da Vinci*¨ procedures were performed in 2011, up 29% from 2010, approximately 450,000 procedures were performed in 2012, up 25% from 2011.
- On 30/09/12 there were **2,462** *da Vinci*¨ System installed worldwide: 1,789 United States, 400 Europe, 273 Rest of World
- On 31/08/13 there are **2.799** da Vinci robots installed worldwide, of which **2001** in the United States, **443** in Europe, and **355** in the Rest of the World.
- FDA Clearances – Laparoscopic, Thoracoscopic, Prostatectomy, Cardiotomy, Revascularization, Urology, Gynecology, Pediatric, Transoral Otolaryngology
- Target Markets - Urology, Gynecology, Cardiothoracic, General, Transoral Surgery

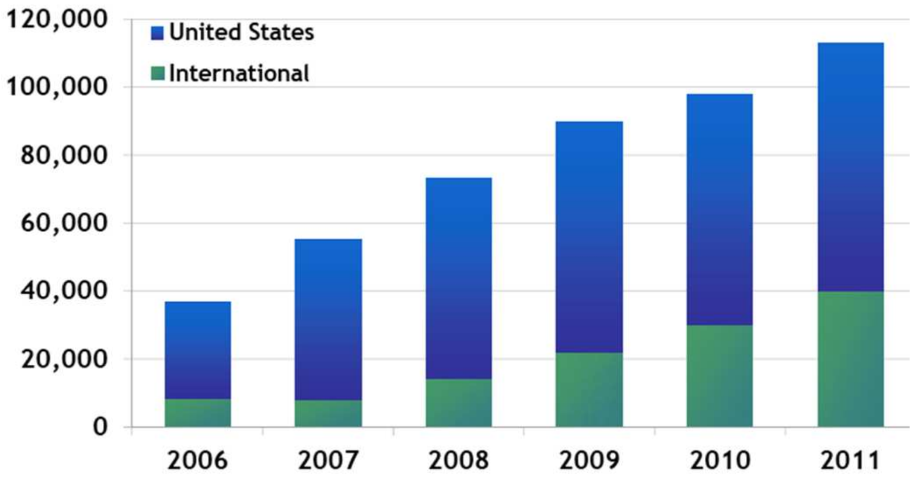
Market Growth



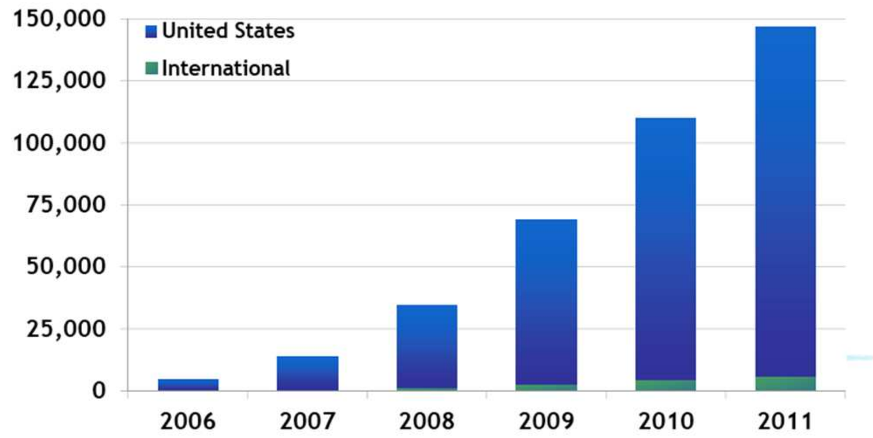
Annual Worldwide Procedures



Da Vinci Systems Installed



Prostatectomy Procedure Growth



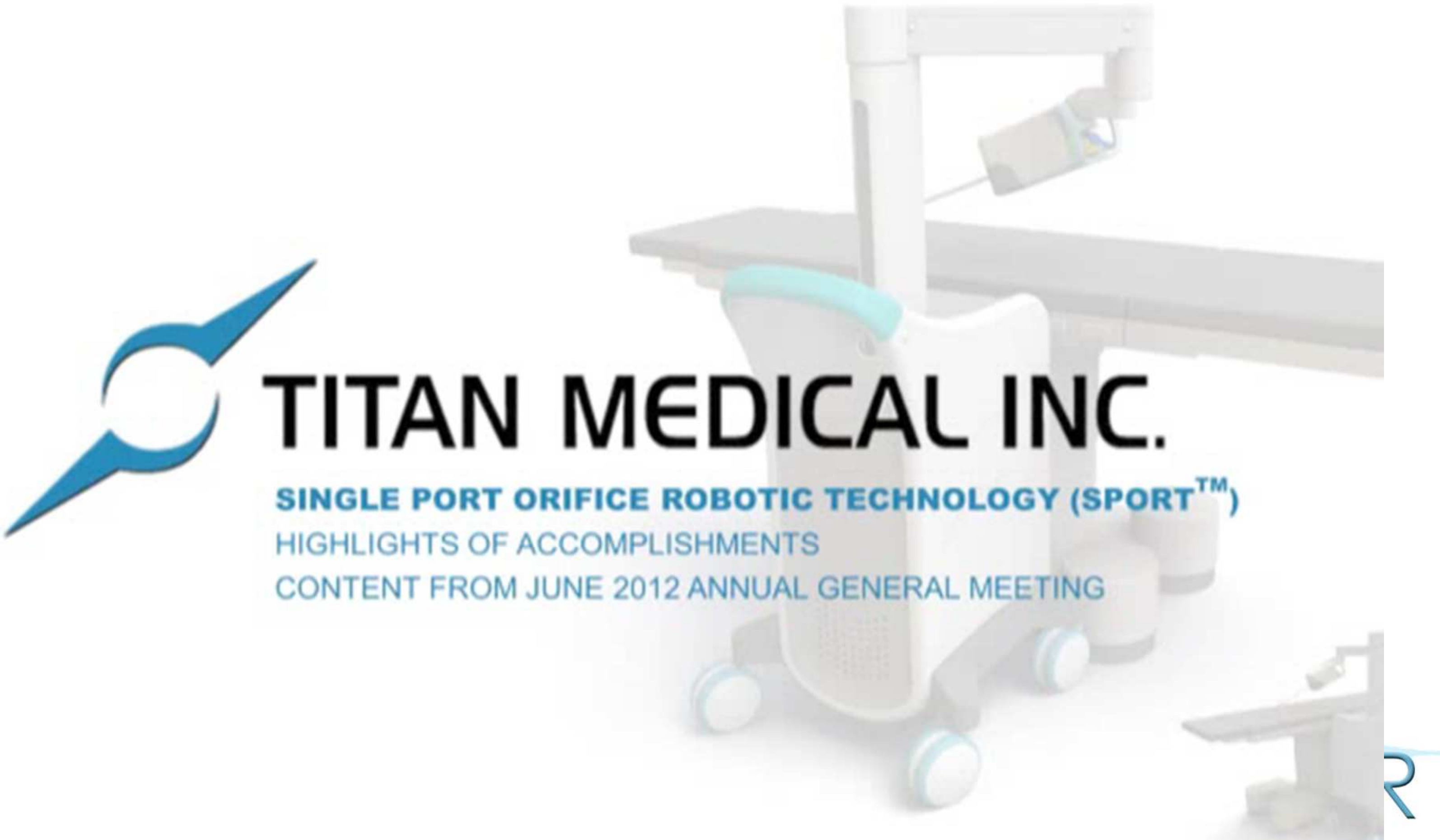
Hysterectomy Procedure Growth

Potential Competitors

- Titan Medical: Amadeus Robot (2014?)

A collaboration between Columbia Professors Peter Allen (Computer Science, Columbia Engineering), Nabil Simaan (formerly Mechanical Engineering at Columbia, now at Vanderbilt) and Dennis Fowler (Surgery, Columbia University Medical Center)

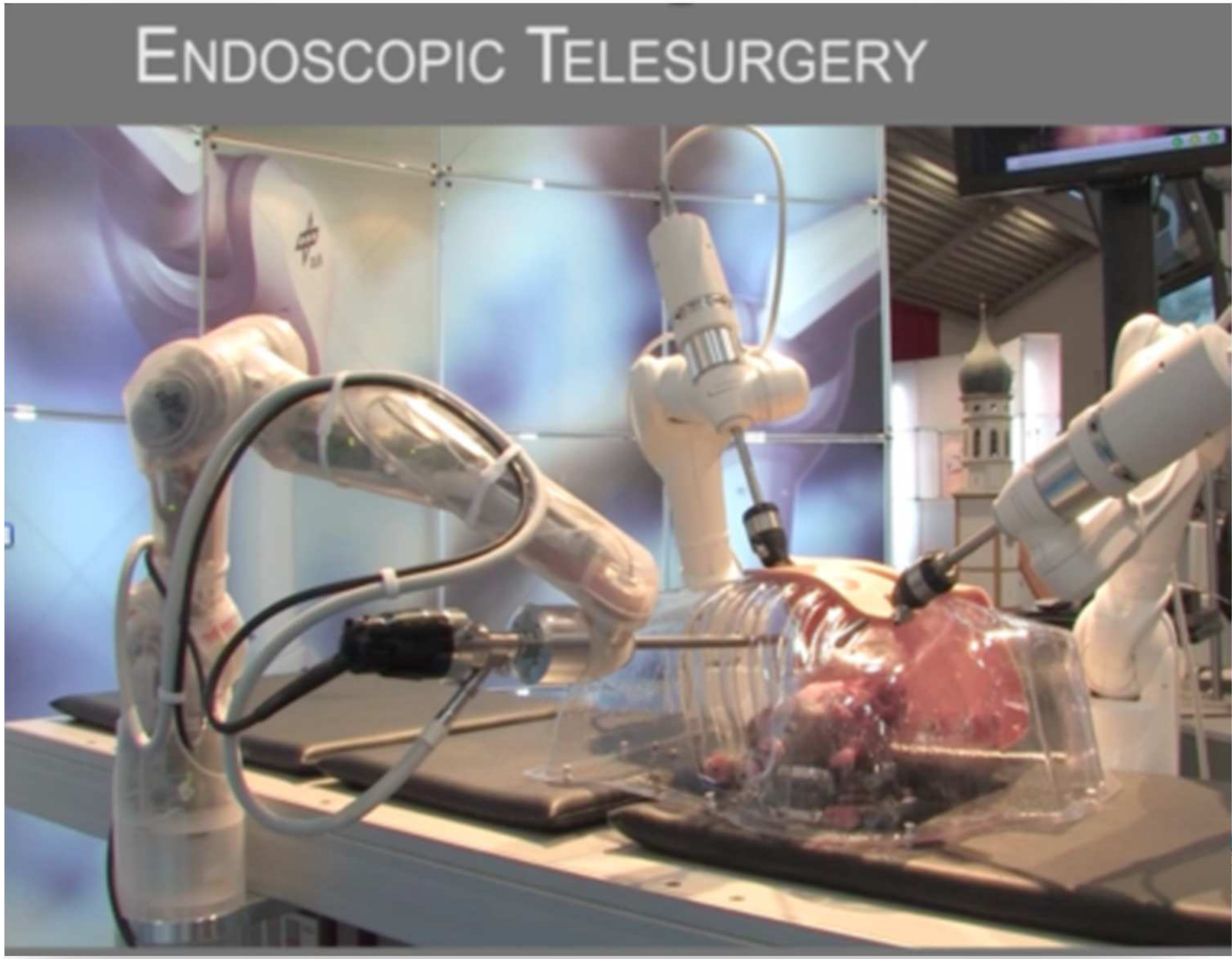
Amadeus Features



Potential Competitors

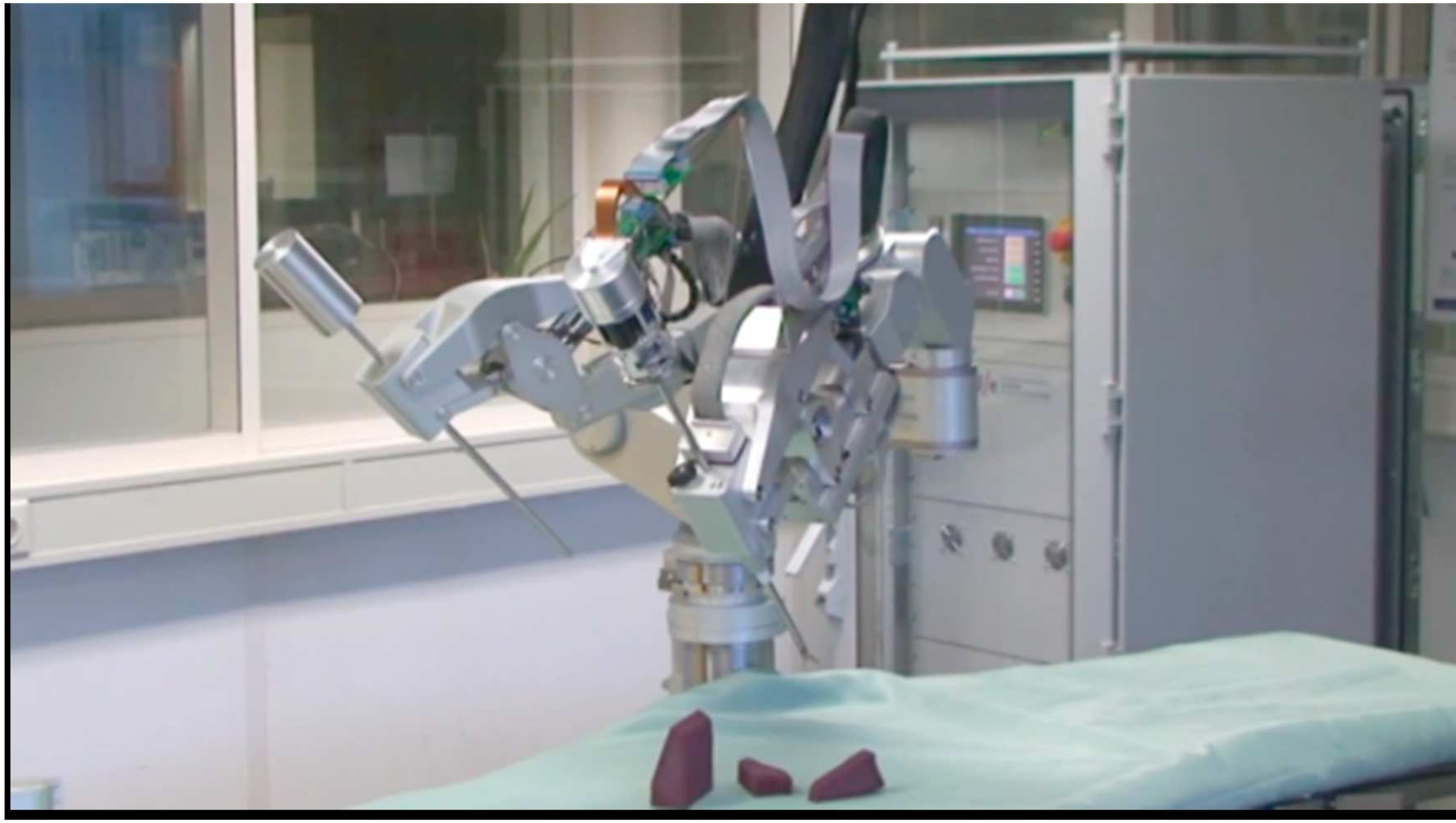
- German Space Agency: MIRO Robot

Miro Features



Potential Competitors

- University of Technology Eindhoven: Sofie Robot



Potential Competitors

- MedRobotics: Cardioarm

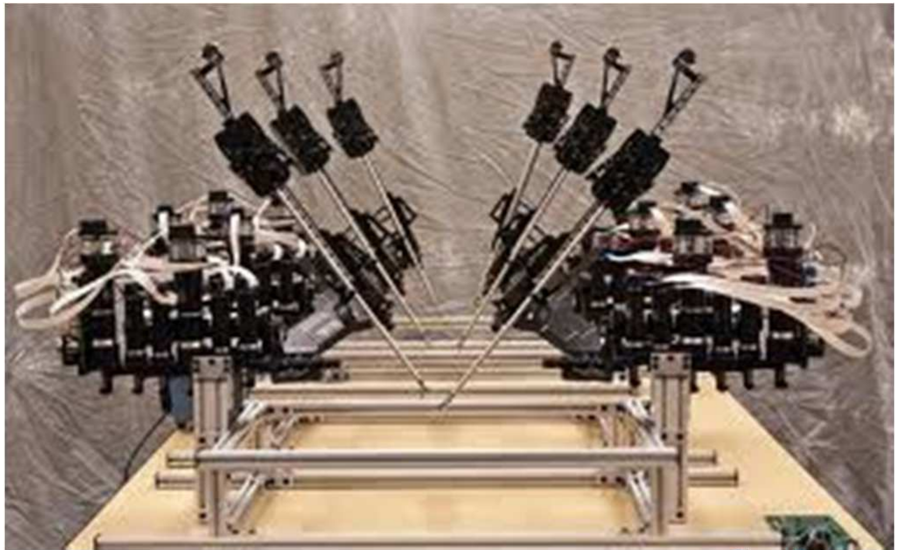
Potential Competitors

- Surgica Robotica: Surgenius Robot

Surgenius Features

Potential Competitors

- University of Washington: Raven robot



A Few Significant Features

- Amadeus and Miro: in development, no animal experiment
- Surgenius: in limbo, but did animal experiments
- Raven: a few copies made for laboratories
- Amadeus, Miro, Raven: NOT certified
- Surgenius: CE certified
- Da Vinci: central column with 4 arms
- Amadeus: single arm
- Miro, Surgenius and Raven: modular structure
- Miro, Amadeus and Surgenius: patented instruments
- Da Vinci: no force feedback
- Miro, Amadeus and Surgenius: force feedback (?)

Limitations of the da Vinci Approach

- MEDICAL (JAMA 2013)
  - Robotically assisted and laparoscopic hysterectomy had similar morbidity profiles, but the use of robotic technology resulted in substantially more costs.
- LEGAL (Citron Research 2012)
  - A track record of excessive and unjustified marketing claims
  - The utter lack of clinical evidence of superior medical outcomes when using its product for surgery, and
  - The gathering storm of legal liability accruing to the company due to its failure to adequately disclose risks prior to its technology causing adverse surgical outcomes, scattered among the hundreds of thousands of surgeries performed with its robotic surgery devices.

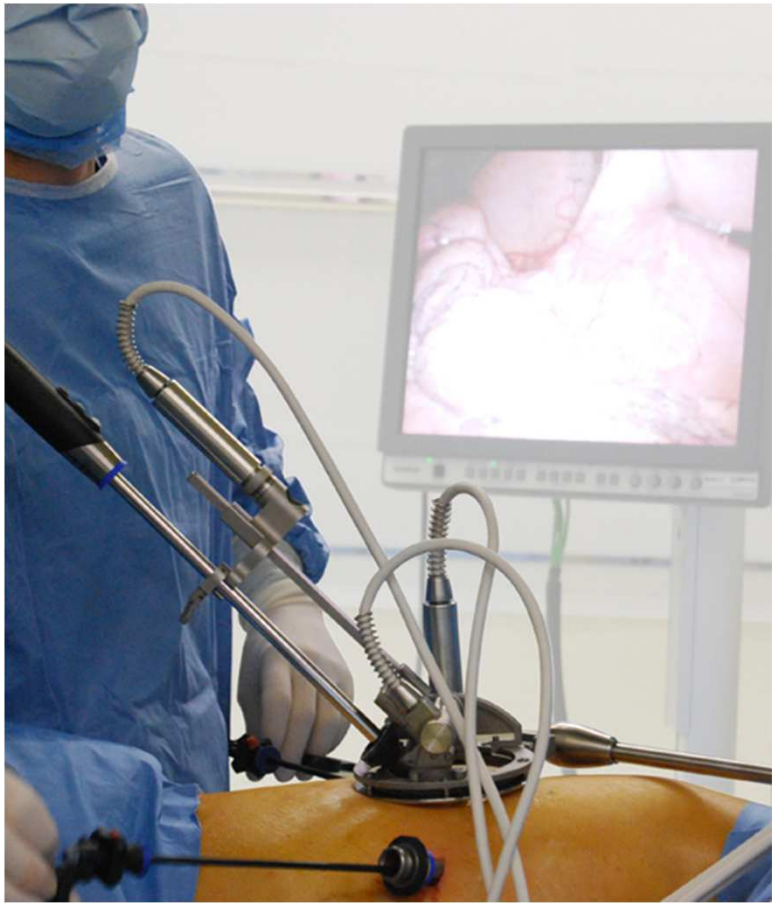
Limitations of the da Vinci Approach

- NETWORK
  - Lack of adequate training (1700 lawsuits pending)
  - Lack of add-on devices and alternative suppliers
  - Lack of involvement of research and medical communities (except a few lucky ones)
- **PATIENT**
  - **Wrong Involvement: asking for technology rather than health care!**
- We need to teach patients to help themselves by making the right choices and not leaving health decisions to market strategists

Future Developments

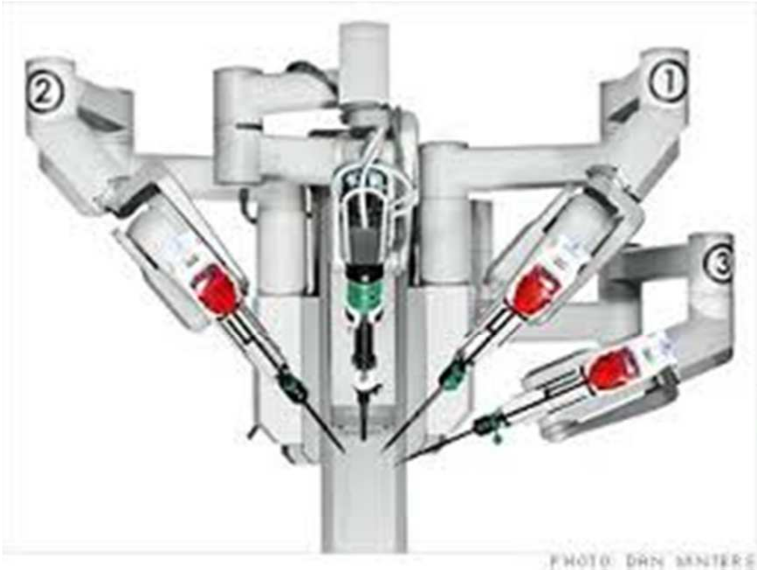
- Focus on three main areas:
  - Design:
    - Mechanics:
      - New common platform
      - Cheaper, interchangeable instruments
    - Software/hardware:
  - System:
  - Technologies:

New Research Platform



- The trend is towards single arm / modular configurations, to accomodate different needs, reduce cost, allow gradual entry into the market.
- Since the "intelligence" is in the instrument, can we use an approach such as Viky (Endocontrol)
- **It is essential to develop a common research platform, otherwise no research result will be ever tested and integrated on a real surgical robot**
- Raven is a good start, but it is still too expensive

Robot Workspace



Da Vinci

Raven

Surgenius

Instruments

Need open interface to connect instruments of different manufacturers

Surgenius instrument

Miro-Mica instrument

©DLR

How difficult is to do this?

- Intuitive Surgical first prototype: 10 years and about 150 Mil US $
- Titan Medical: on going, more than 100 Mil Can $
- DLR Miro Surge System: 6-7 years a few Mil €
- Surgica Robotica: 3 years 3.5 Mil €

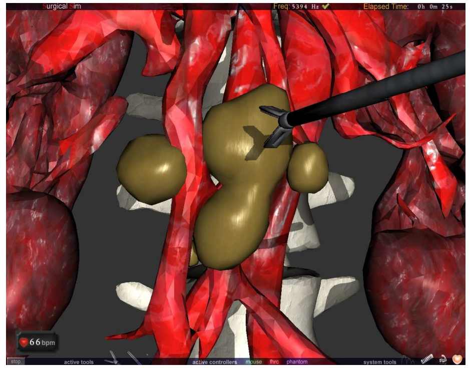
Surgica Robotica Approach

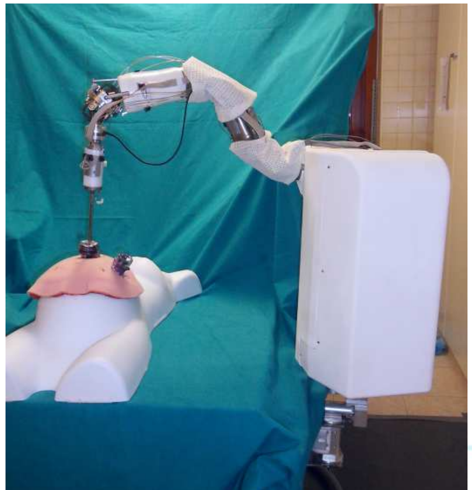
SEVENTH FRAMEWORK PROGRAMME

SURGICA ROBOTICA
Medical Technology Solutions

JPL
Jet Propulsion Laboratory
California Institute of Technology

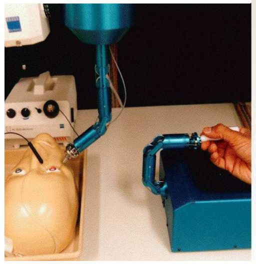
NASA





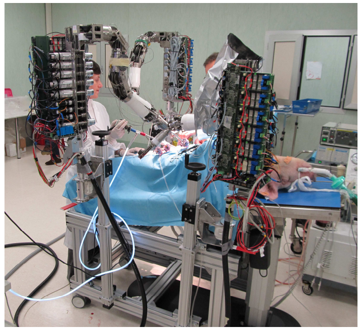
Development Time Scale

RAMS

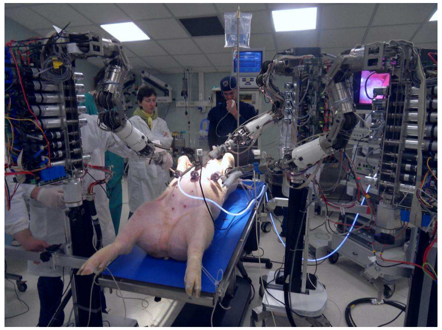


Alfa

Beta.0



Beta.1



Gamma

Design phase

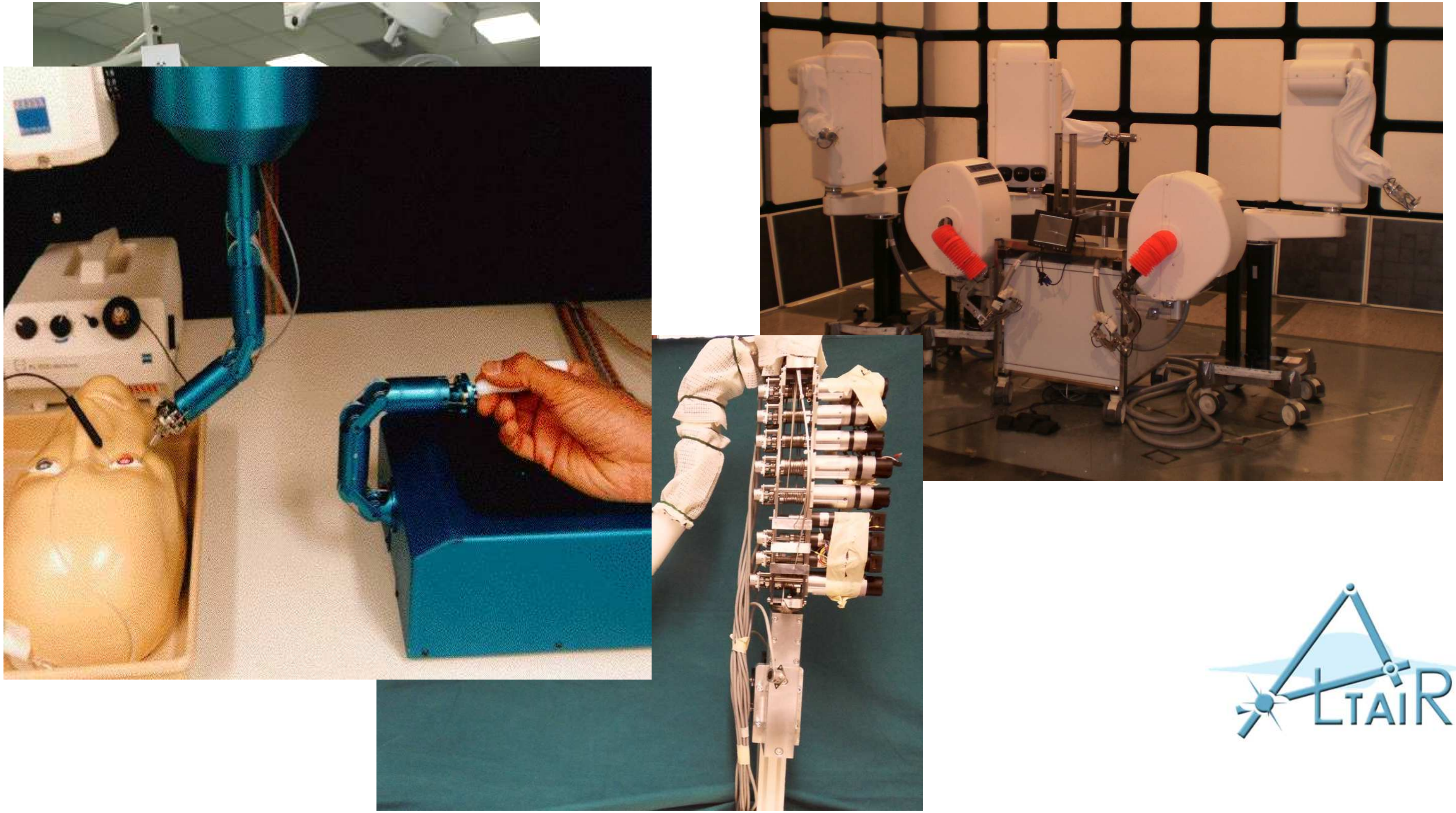
NASA R&D — Universita' di Verona R&D — Alpha design and fabricaiton — Beta design and fabricatiion — Validation — CE Mark

90's — 2009 — 1Q2010 — 3Q2010 — 1Q2011 — 2Q2012

SURGICA ROBOTICA established

Less than 1 year per design/fabrication/validation cycle

Surgenius Prototypes



Future Developments

- Focus on three main areas:
  - Design:
    - Mechanics:
    - Software/hardware:
      - Standardization efforts
      - Benchmarks and validation
  - System:
  - Technologies:

Software/hardware modularity

- Necessary to increase robustness and system flexibility
- Will increase competition and reduce prices
- But……
- It is currently not "legal" because of regulations and
- Not possible because technologies are missing.
- It is an important area of scientific and legal research

EIC-ISO Safety Standards

- Industrial Robots

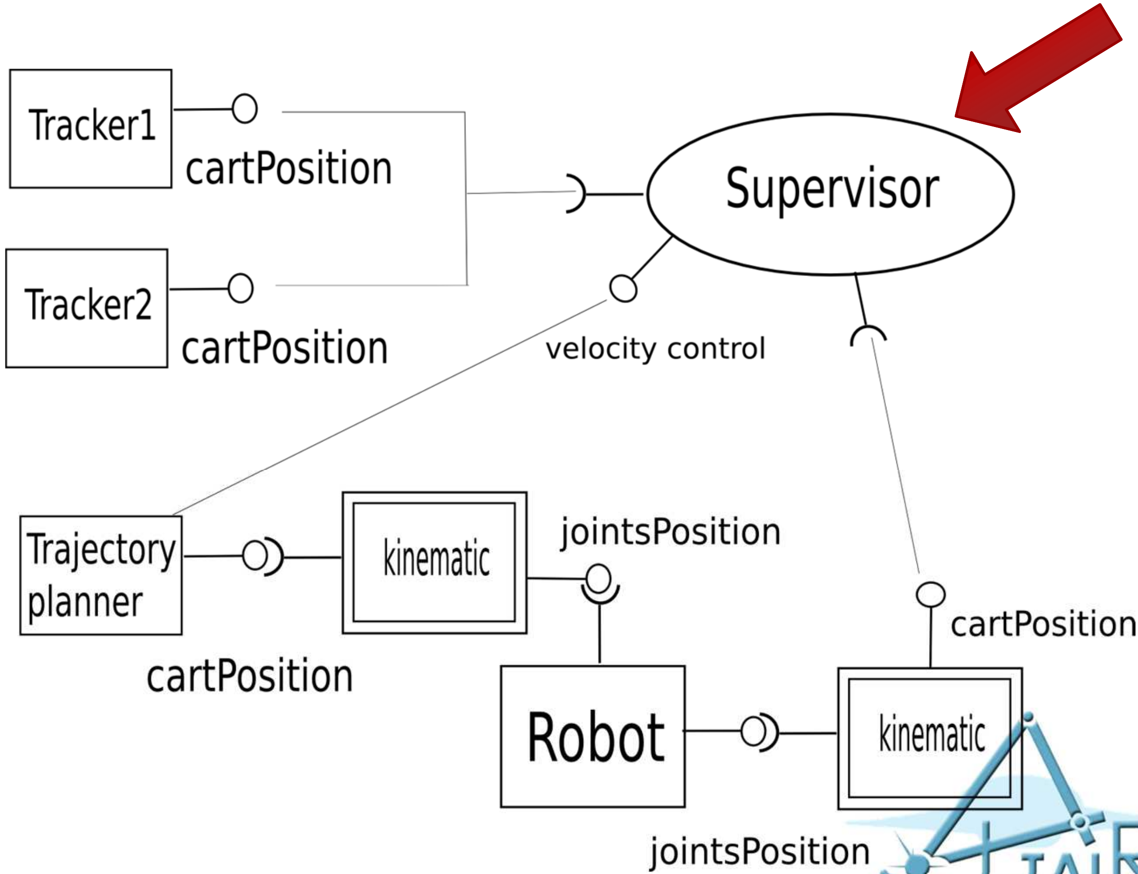
- Mobile Service Robots
- Person Carrier Robots
- Wearable Assistant Robots
- Medical Robots

- ISO-IEC Technical Committee 184 Joint Work Group 9 is developing a new standard for medical equipment using robots: the initial work has identified "autonomy" as the only key difference with ordinary medical equipment. Analysis and discussions are on going on how to ensure safety in this case.

Ontology- Based Design and Verification

- Eurosurge: www.eurosurge.eu
  - Automatic generation of Orocos components from system and task ontologies
  - New type of Orocos component with internal supervisor to monitor input/output data
  - Same ontologies define a validation procedure that assesses data consistency of heterogeneous modules
  - Benchmarks used to define nominal system performance and new performance in case of module replacement

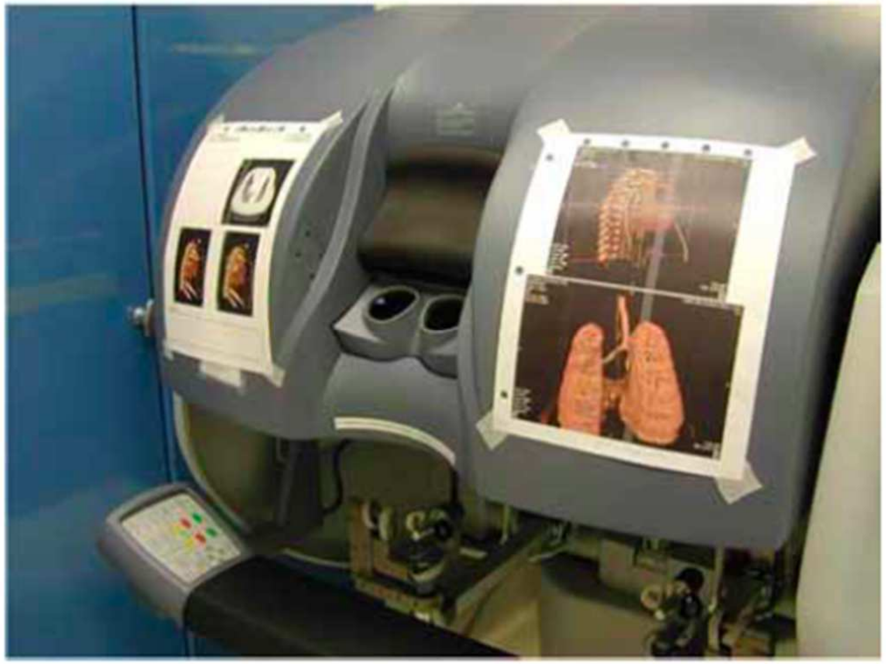
Method Demonstration



Future Developments

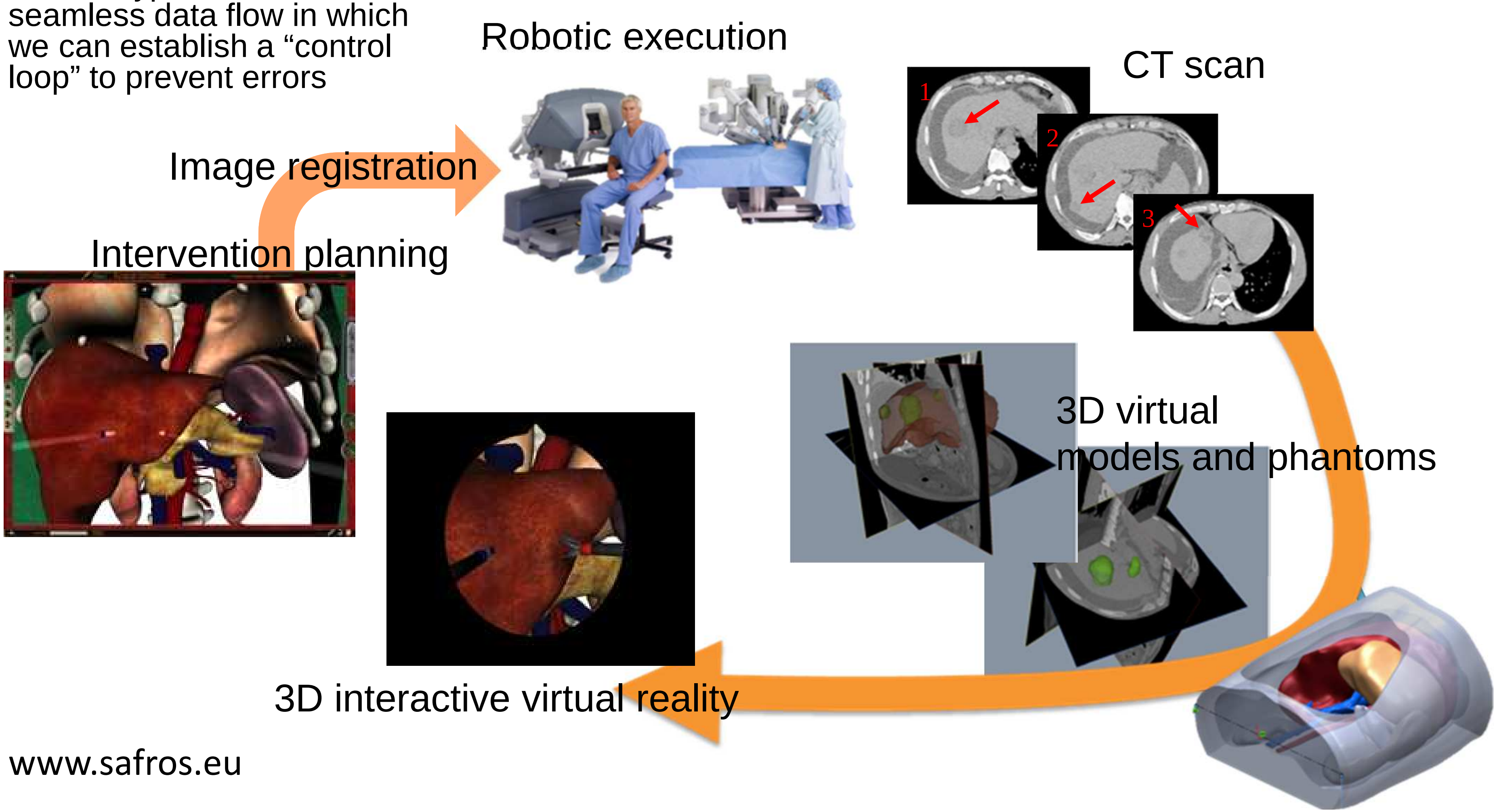
- Focus on three main areas:
  - Design:
    - Mechanics:
    - Software/hardware:
  - System:
    - Workflow analysis
      - Identification and analysis of steps
      - Modeling and control
  - Technologies:

Typical Data Integration



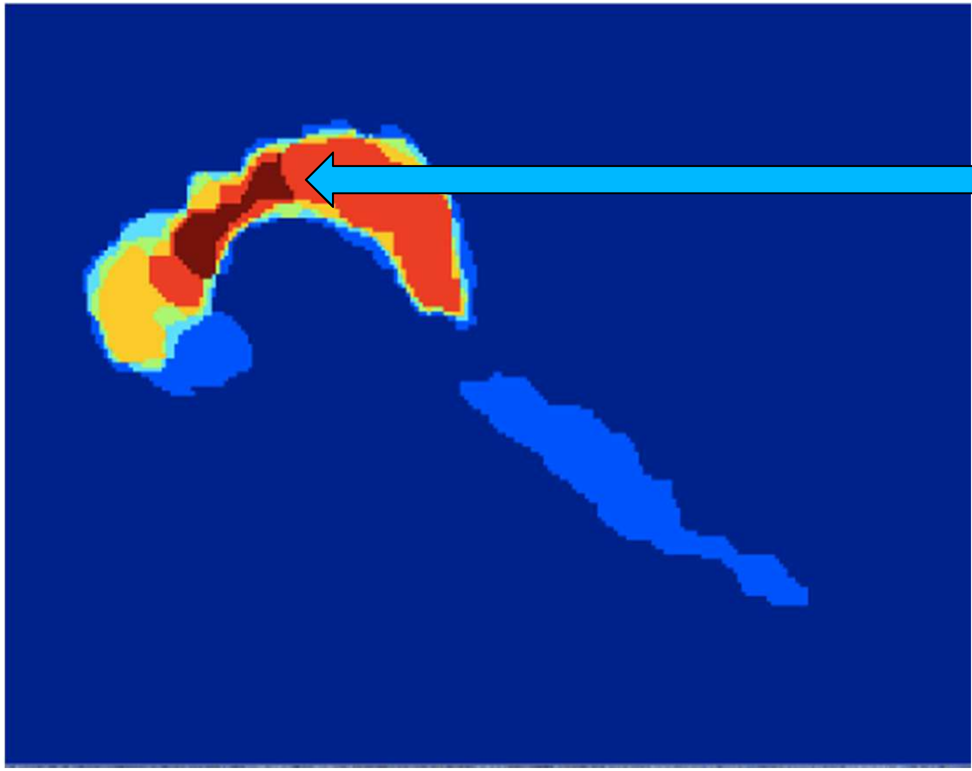
Workflow in robotic surgery

Safros Hypothesis: a seamless data flow in which we can establish a “control loop” to prevent errors



Example: Diagnosis

Diagnostic Safety: pancreas segmentation

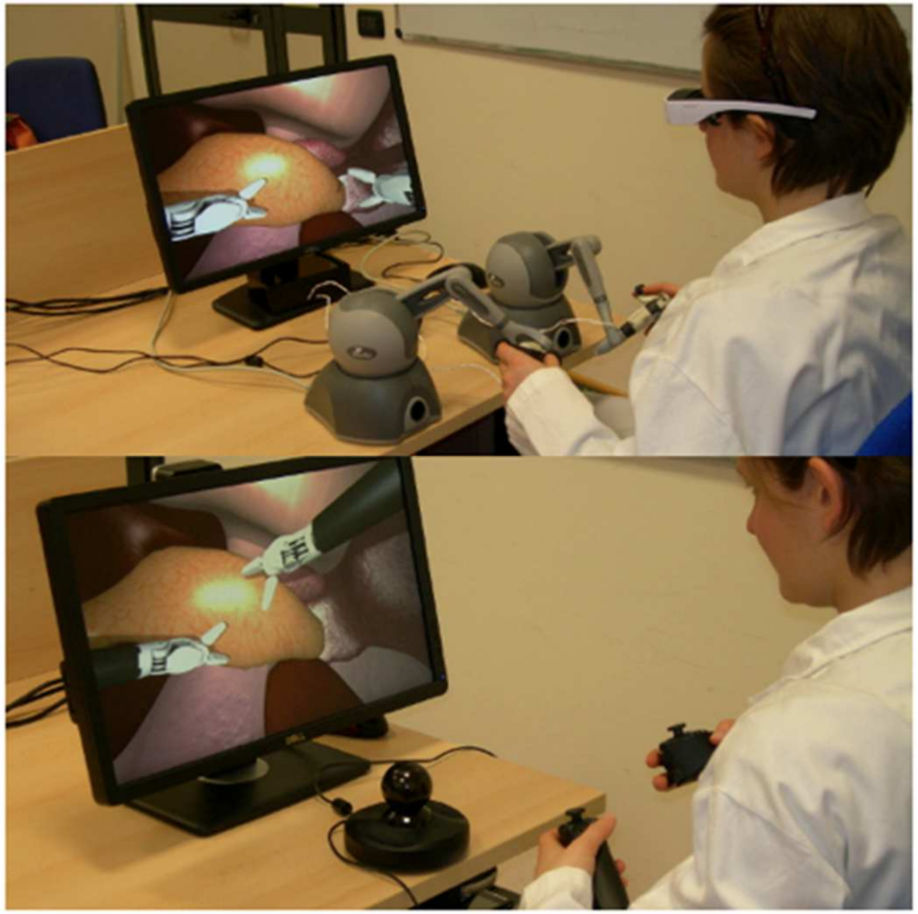


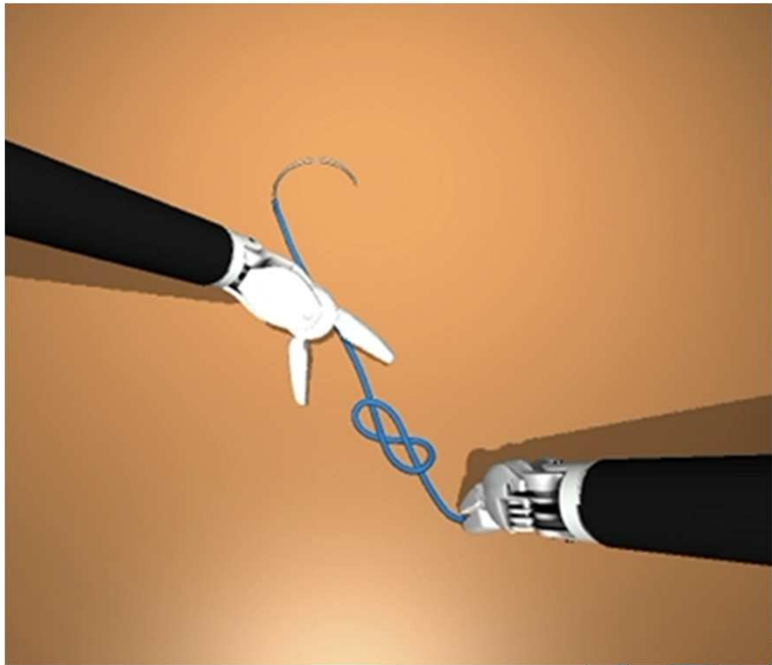
This is the only area
that all 6 radiologists
agreed to be healthy

Model generation depends on the radiologist: unknown factors influence such largely different diagnosis

Example: Training

Quantification and predictive value of training





Workflow Analysis

- A complete medical process involves many people and long time
- **Information, actions, decisions and devices may interact unexpectedly**
- **Measurements, situation awareness, machine perception, automatic learning should be modeled and should interact (how? when?) with the humans acting on the process.**

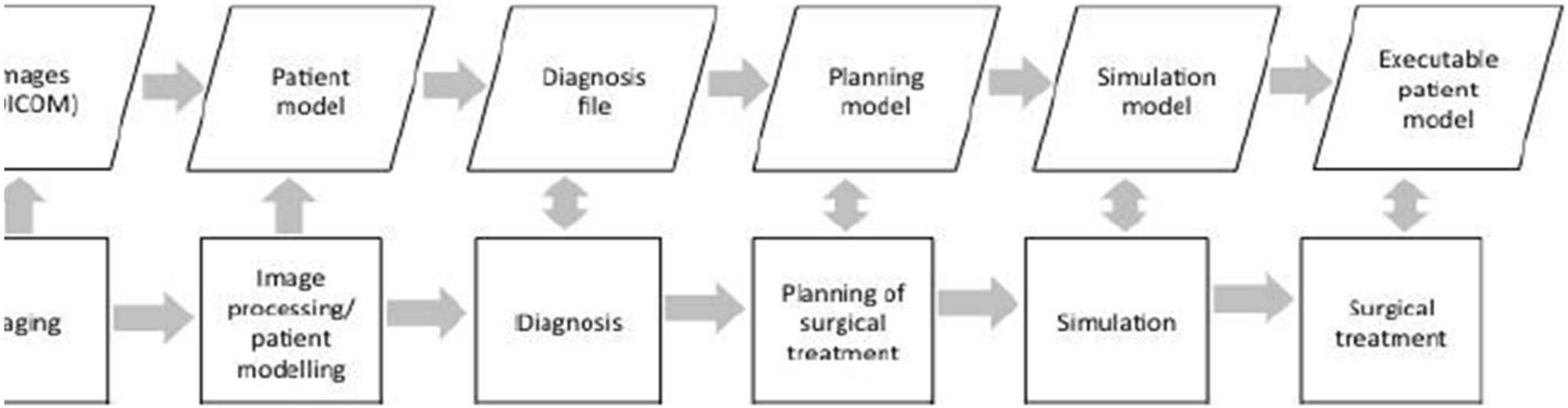
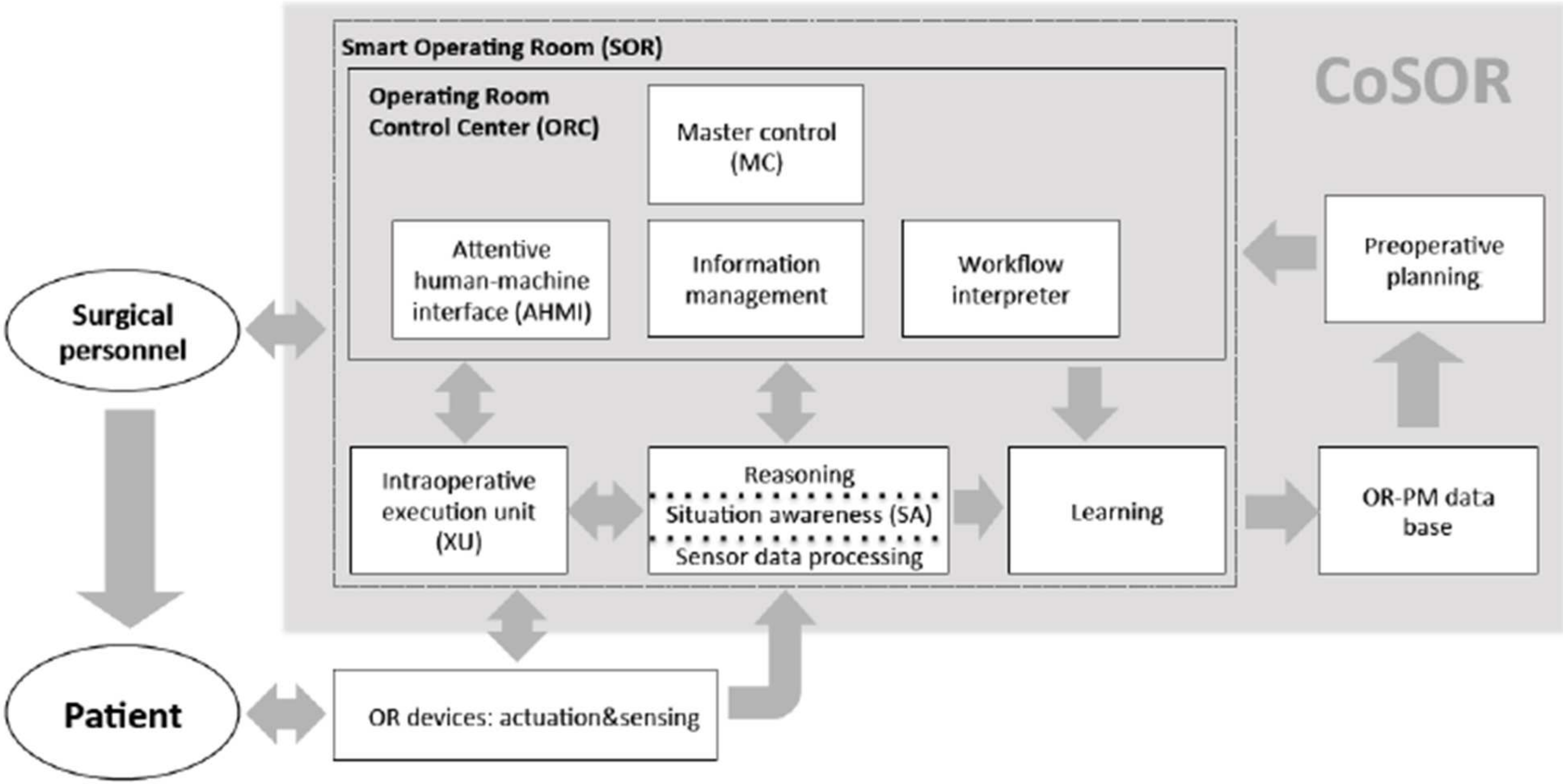


Figure 1.1 - Dataflow (upper row) along the physical workflow (bottom row)

Workflow Control



Execution and control of a complex workflow

Future Developments

- Focus on three main areas:
  - Design:
    - Mechanics:
    - Software/hardware:
  - System:
    - Workflow analysis
  - Technologies:
    - Anatomical modeling
    - Navigation and registration
    - Automation in surgery
    - Simulation and training

Technology Challenges

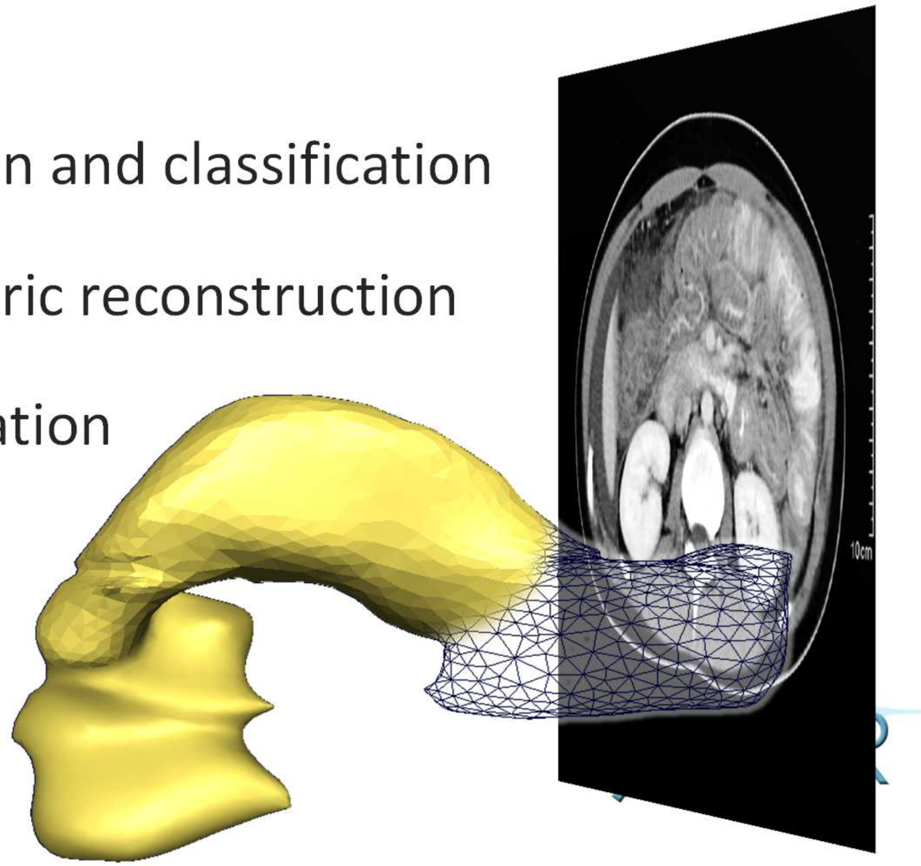
Surgical field is a challenging environment:

- Partial/approximate knowledge of patient anatomy
- Reduced or no direct view of the intervention field
- Small structures and reduced dexterity
- Delicate structures and fragile tissues

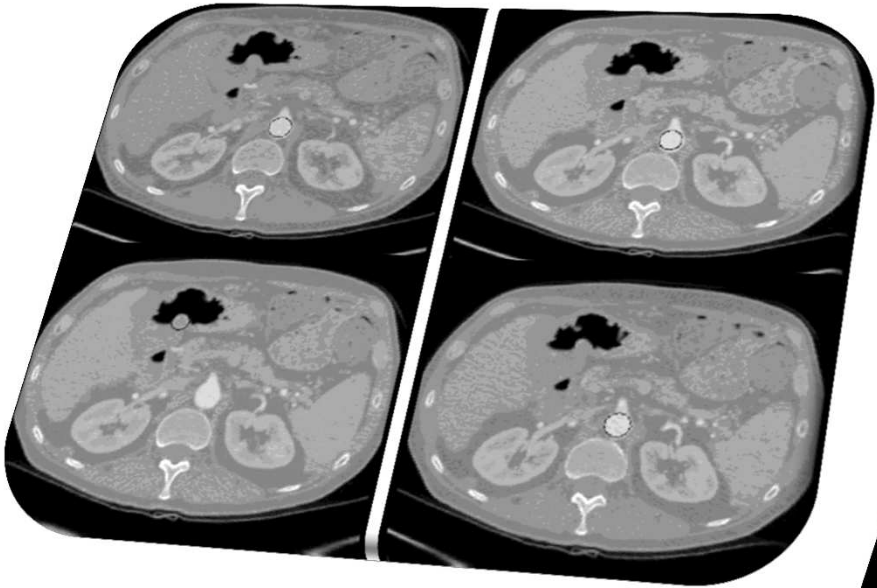
Medical data analysis

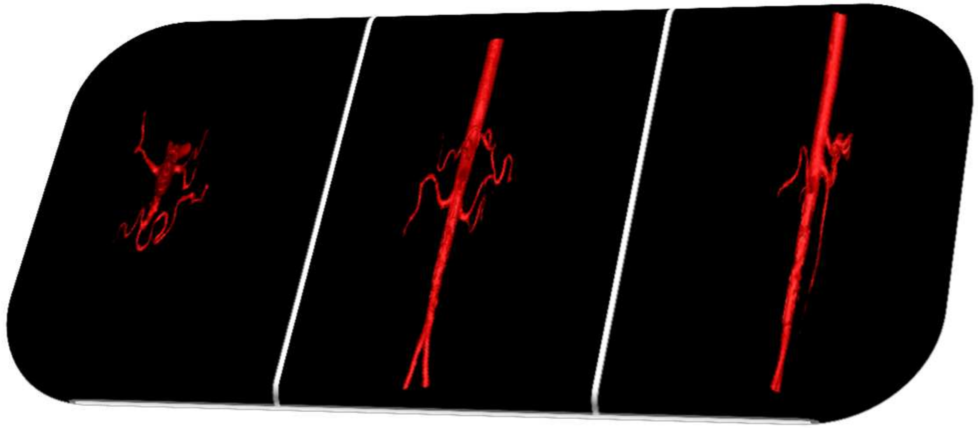
Diagnosis and surgery planning are based on images
➔ Tools for:

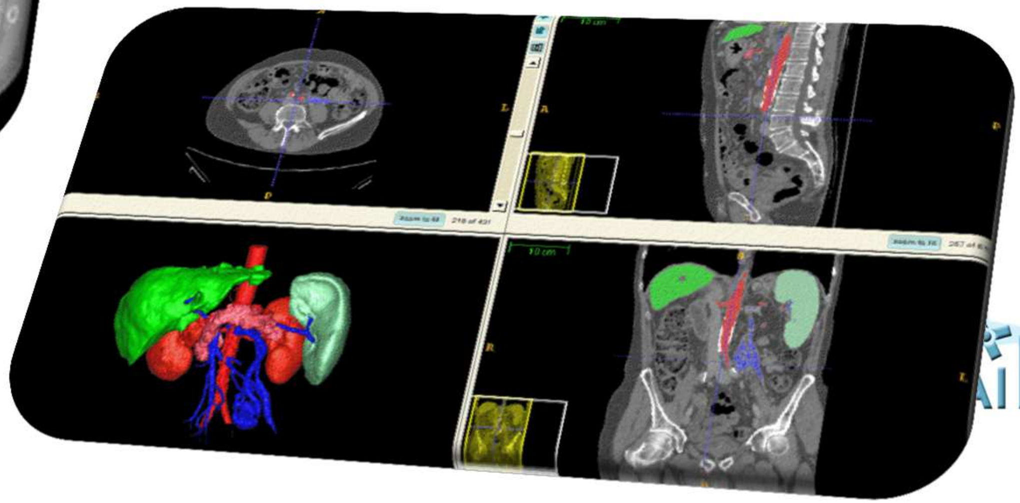
- Image segmentation and classification
- Structures volumetric reconstruction
- Intervention simulation
  - Physical models
  - Virtual models



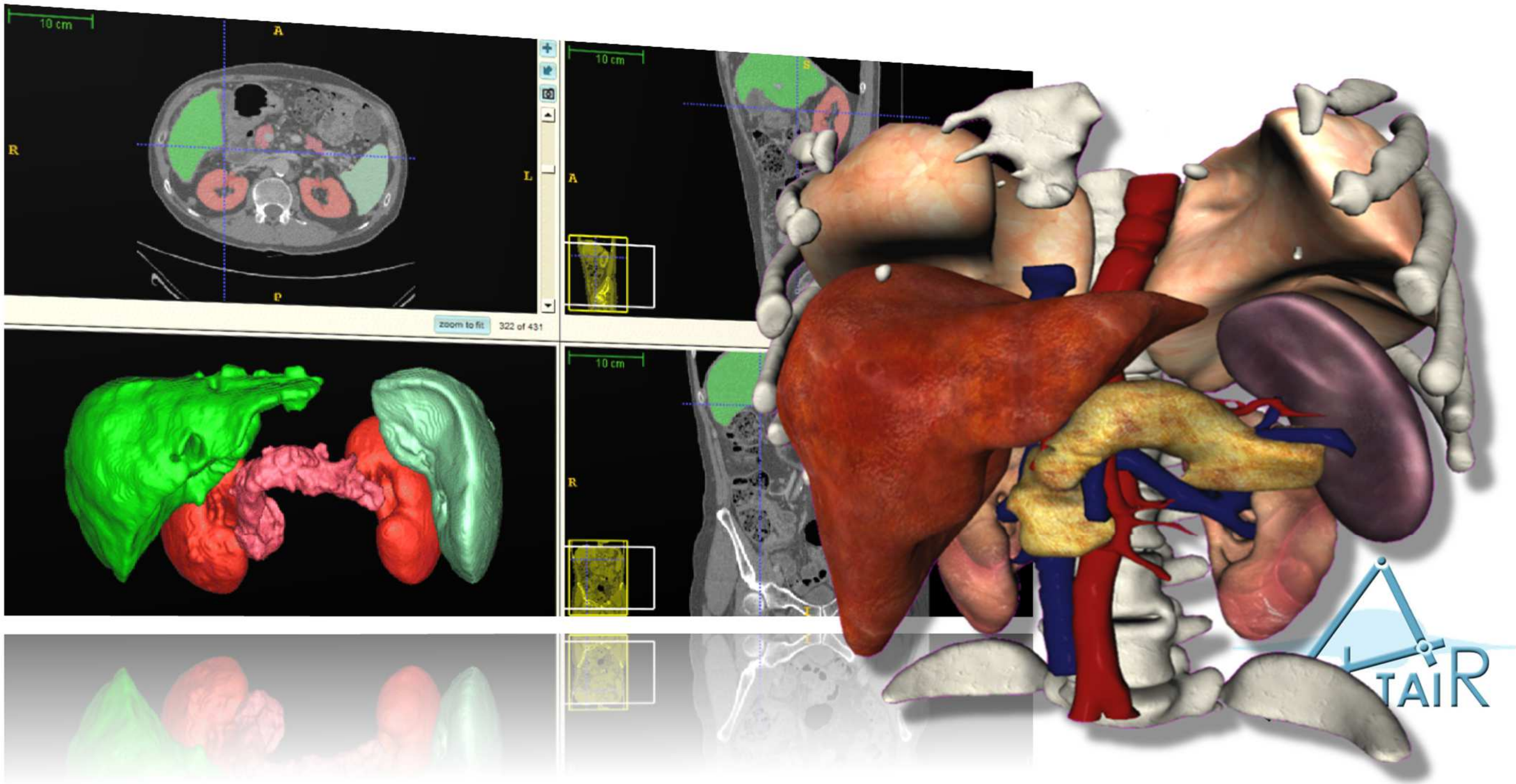
Anatomy reconstruction





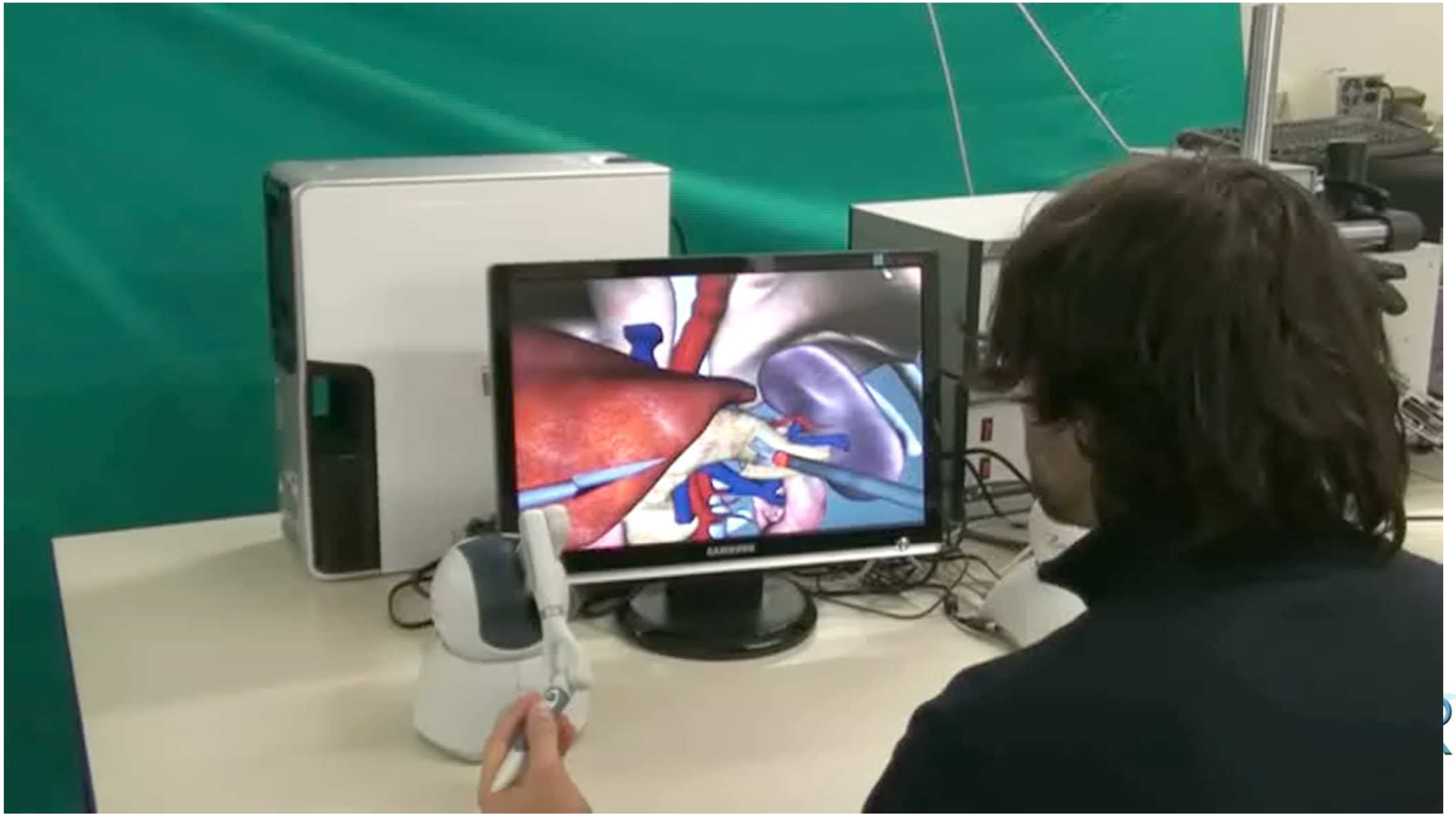


Anatomy reconstruction



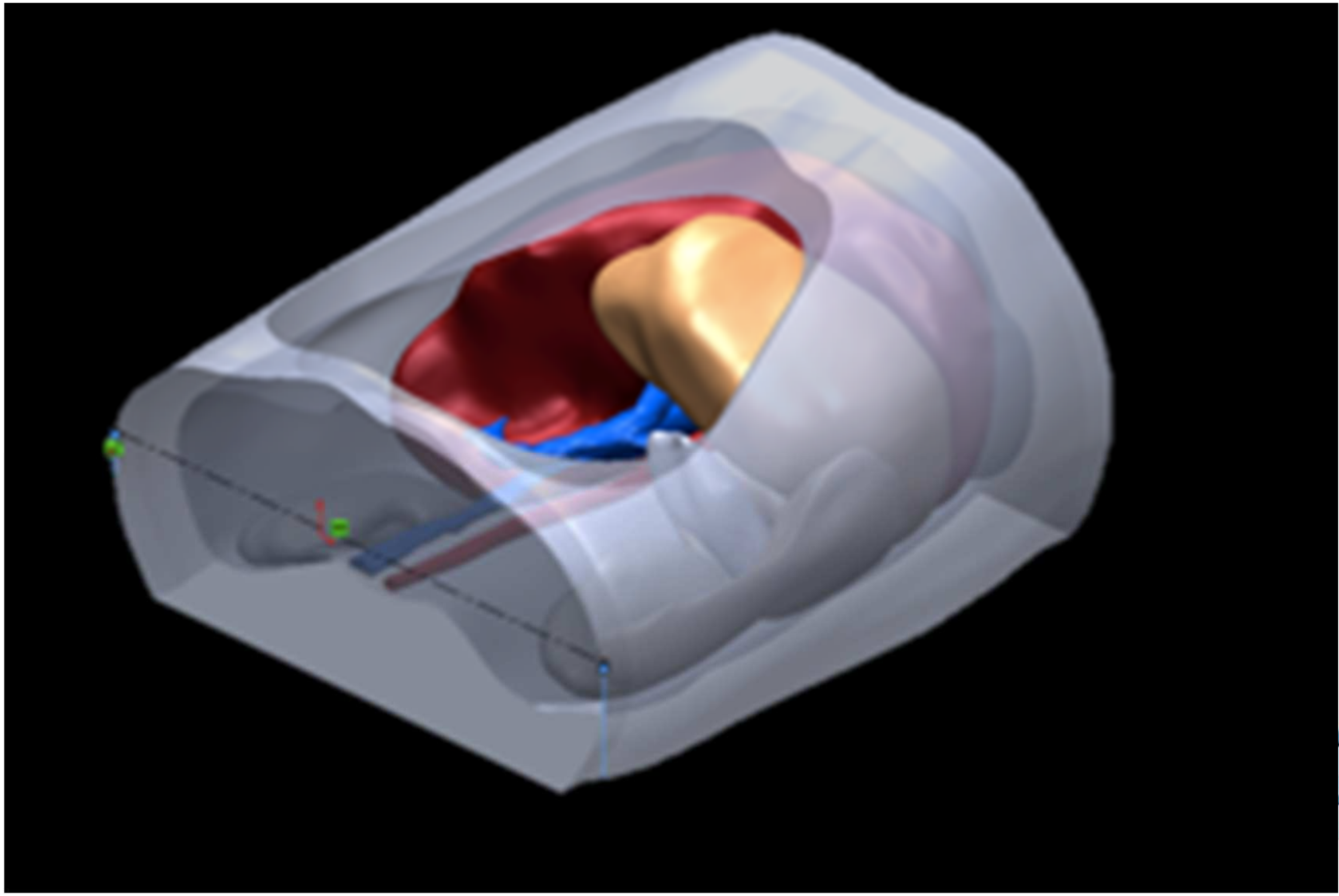
Organ simulation

Intervention simulation



Intervention simulation

Physical Models (Phantoms)



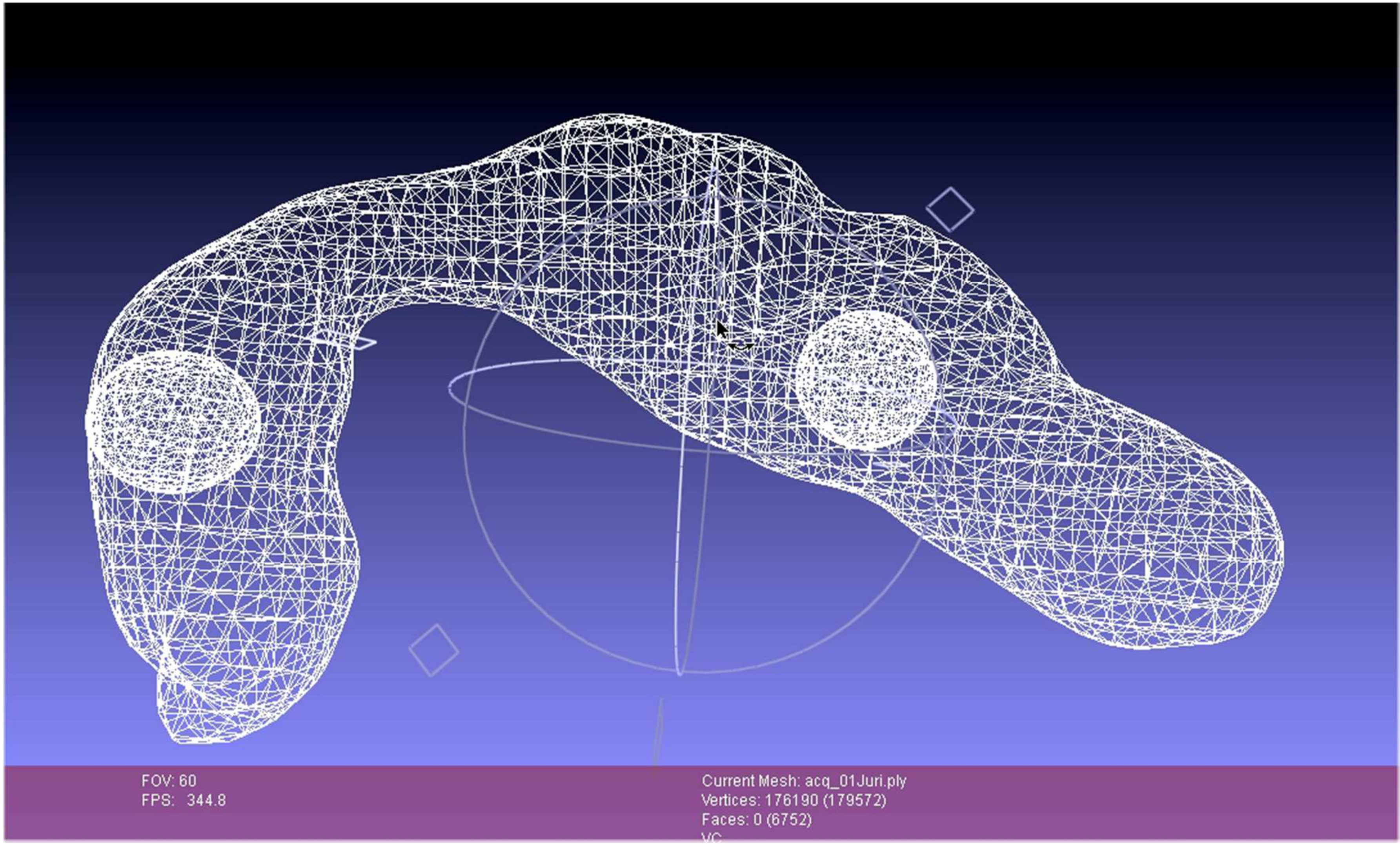
Data registration

During the intervention patient anatomy changes (because of breathing motion, changes in position, …)
➔ Tools for:

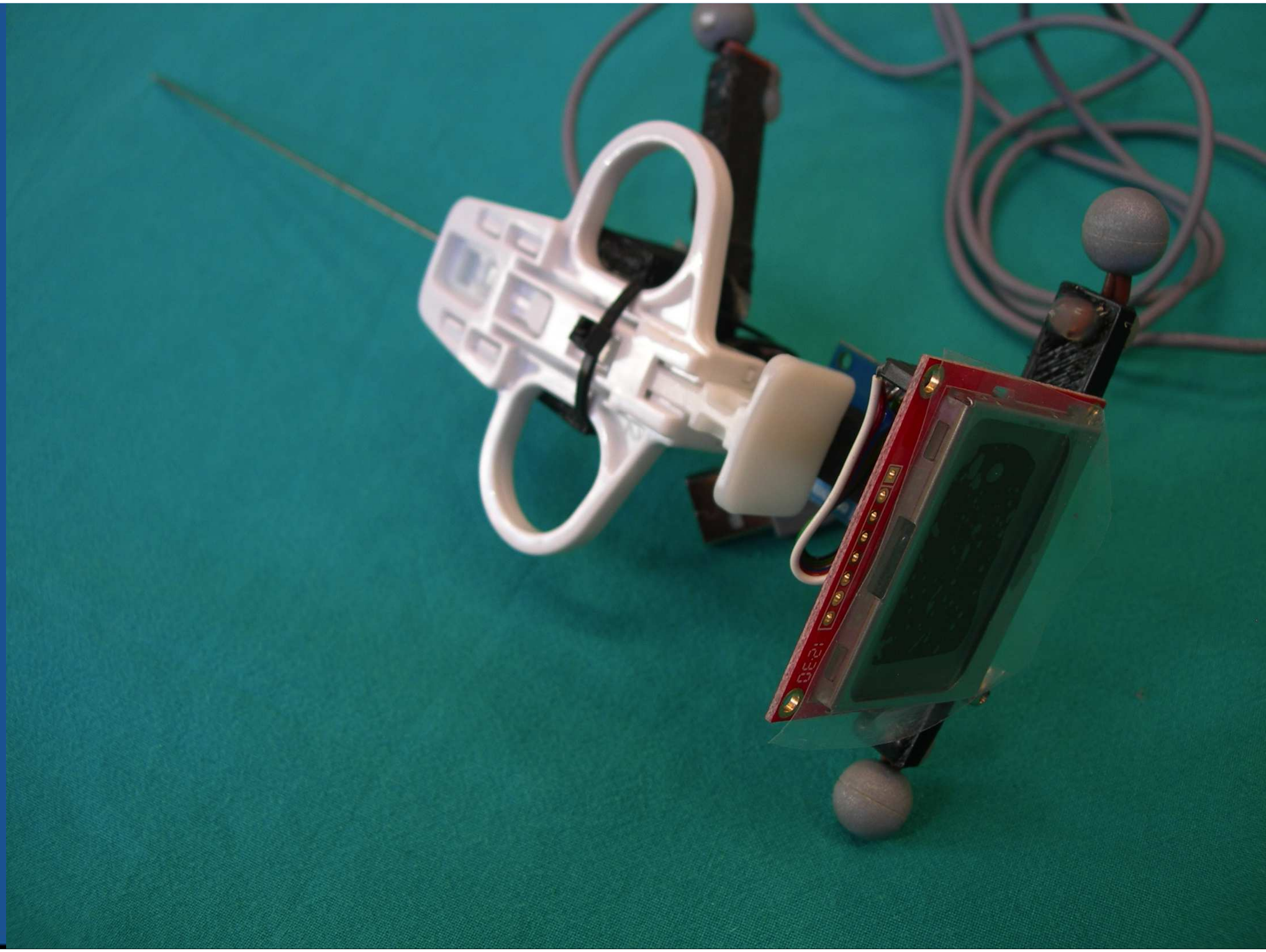
- Registration of patient with pre operative data
- Registration of intra and pre operative data
- “Navigation” during the intervention

Data fusion and registration

Data fusion and registration



Surgical navigation in biopsy



Intelligence in Surgical Robotics

Robots have been successfully introduced in surgery, however they have little machine intelligence, yet:

- Step by step planning
-

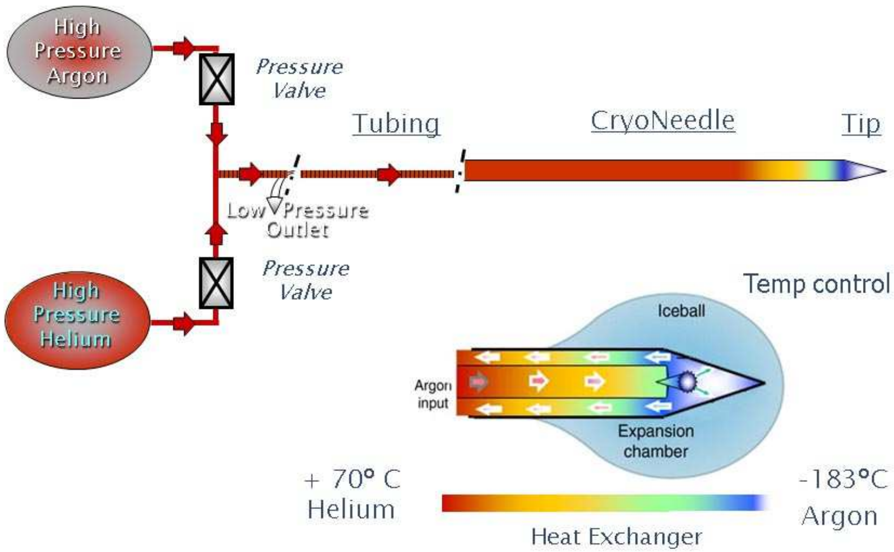
→ Need for as

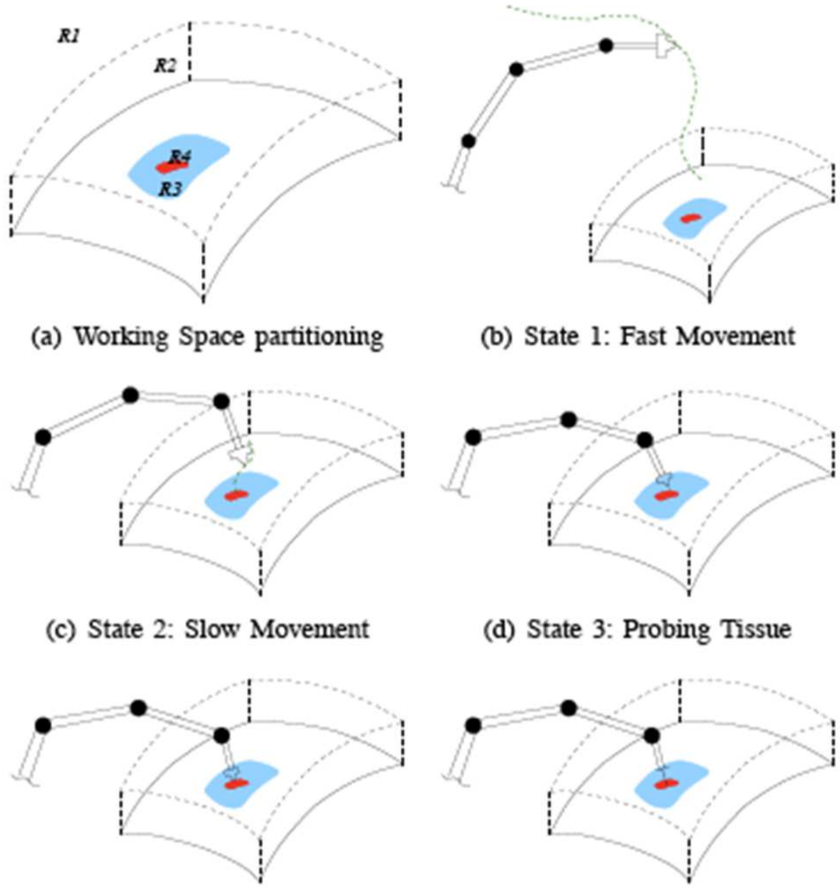
Autonomous surgical actions

Automation of some surgical tasks:

- Cryoablation, suturing, …
- A cognitive system learns from surgeons movements, abstracts the task, and extends it to different anatomies and conditions
- The system autonomously plans and executes the intervention under the supervision of the surgeon

Autonomous surgical actions





(a) Working Space partitioning (b) State 1: Fast Movement

(c) State 2: Slow Movement (d) State 3: Probing Tissue

(e) State 4: Perpendicular Attitude (f) State 5: Puncturing

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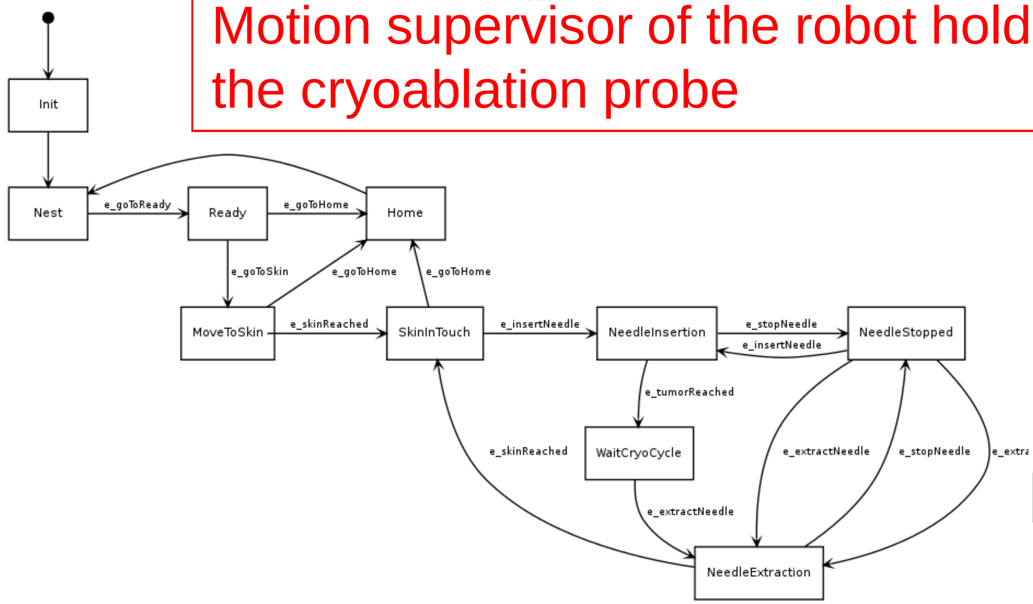
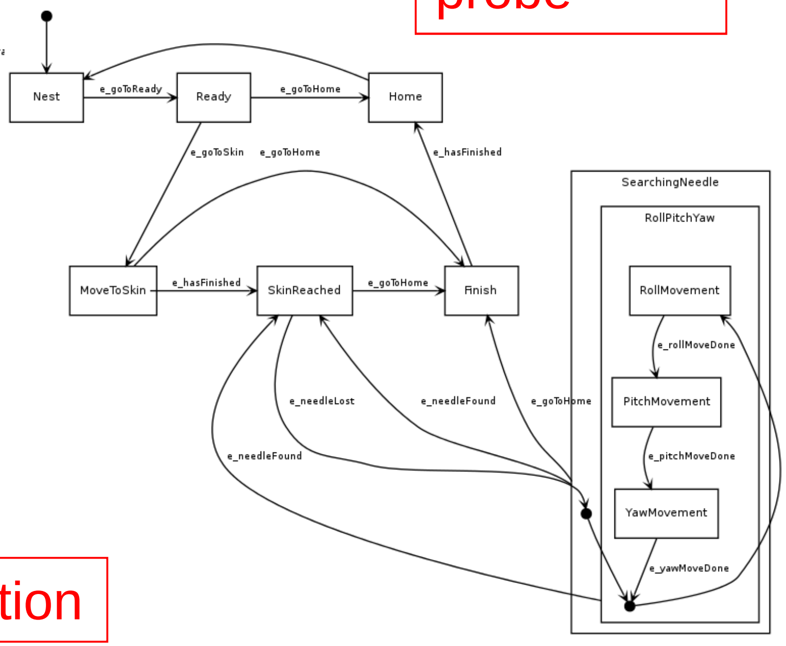
INTELLIGENT SURGICAL ROBOTICS

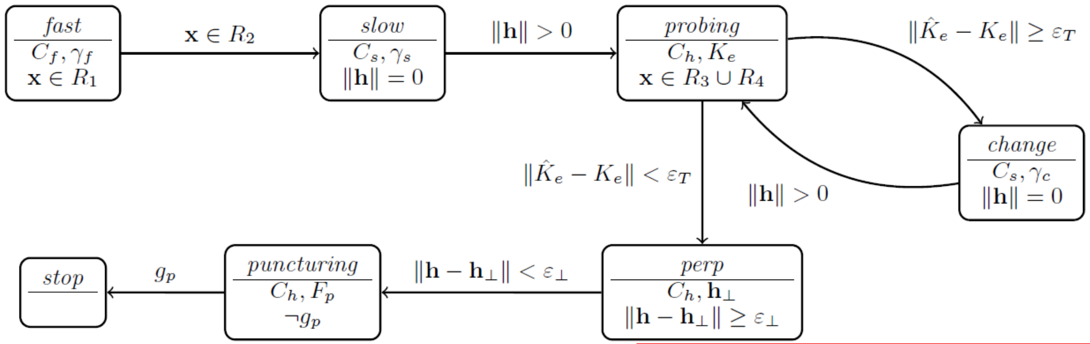
Autonomous surgical actions

Motion supervisor of the robot holding the cryoablation probe



Motion supervisor of the robot holding the US probe

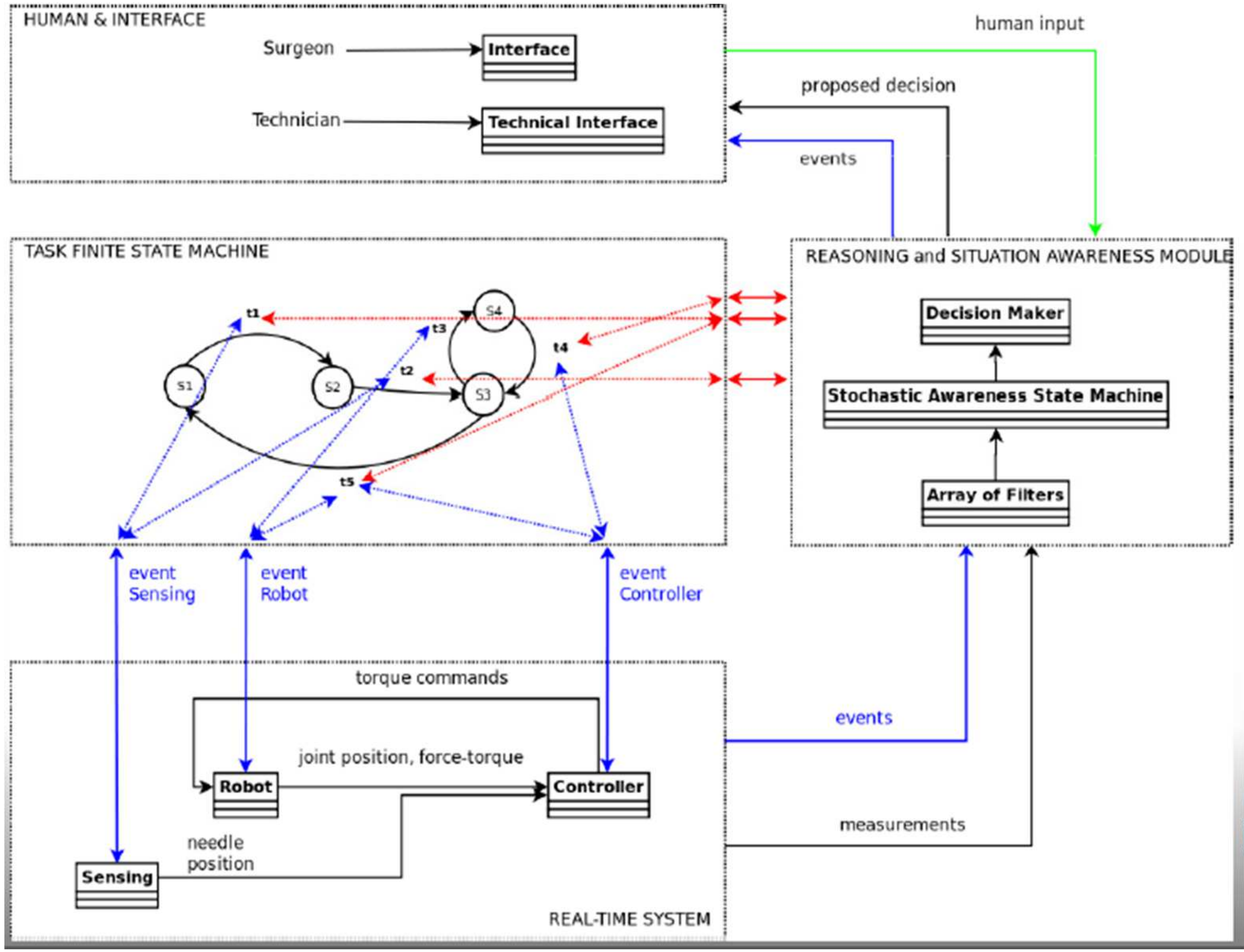




Formal plan verification

Autonomous puncturing

Reasoning and Automation



Training in robotic surgery

Virtual Fixtures

Economic Challenges

Will these technologies ever reach the Market?

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Thanks for

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